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(19)



## (54) STERILISING BAG

(71) We, IMPERIAL CHEMICAL INDUSTRIES LIMITED, Imperial Chemical House, Millbank, London SW1P 3JF, a British Company, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

10 This invention relates to an improved sterilising bag, and to a sterilisable bag package formed from such a bag.

Surgical items, for example instruments and catheters, must be sterile in use, and are usually enclosed in a package in which the item is capable of being sterilised and kept sterile. Such packages are known as sterilising bags and usually consist of a sheet of paper, permeable to gas and steam but capable of acting as a bacteria filter, and a sheet of transparent thermoplastics material, generally impermeable to gas or steam. The bag is made by heat sealing the two sheets round their edges apart from at an opening. In use, the item to be sterilised is placed in the bag, the open area closed by a heat seal, and the whole package exposed to steam or a sterilising gas. The steam or gas enters the package through the paper and sterilises the contents which remain sterile by virtue of the paper acting as a bacteria filter. To release the item the paper and thermoplastics material sheets are torn apart by hand along the heat formed seals to expose the packed item.

British Patent Specification 1329940 describes a sterilising bag in which, when in the closed form, a packed article can be accommodated in a pocket formed from thermoplastic film within the bag to protect the article during the opening of the bag.

According to the invention there is provided a sterilising bag comprising, in its open form, two substantially flat and flexible sheets of approximately the same size, of

which one is made of paper being gas- and steam-permeable and capable of serving as a bacteria filter and the other is made of practically gas- and steam-impermeable thermoplastics material, and a third sheet, 50 having a smaller extension in one direction than the other two sheets and made of a laminate composed of a layer of thermoplastics material and a layer of paper united together; the first two sheets being united 55 together in register with the third sheet between them by a heat formed seal along lines describing a polygon with one side missing such that the thermoplastic material layer of the laminate is united to the paper sheet 60 and the paper layer of the laminate is united to the thermoplastics material sheet, and wherein the third sheet terminates inside and sealing line polygon for a part of its circumference remote from the unsealed side 65 of the polygon, and is not sealed to the other two sheets along this part of its circumference.

In the present sterilising bag, the third sheet is made from a laminate composed of 70 a layer of thermoplastic material and a layer of paper united together, and the bag is united only by paper-thermoplastic material heat-formed seals.

It will be observed that the sterilising 75 bag of the invention forms two pockets within the bag when it is closed into a package. In principle, the packed article can be accommodated within either pocket. In practice, however it is preferred that the 80 packed article be accommodated in the pocket formed between the thermoplastics material sheet and the laminate since not only is the packed article visible, but when the paper sheet is peeled away from the base 85 of the pocket, the article is left in the pocket until the paper sheet is peeled back beyond the open end of the pocket.

The invention also provides a sterilisable bag package comprising a sterilising bag 90

of the invention including a packed article within the bag and a heat formed seal along the unsealed side of the polygon to complete the seal around the packed article.

5 In order that the invention may be more clearly understood, a preferred embodiment of the sterilising bag will now be described by way of example only with reference to the accompanying drawings of which:—

10 Fig. 1 is a plan view of the bag in the open form,

Fig. 2 is a section along the line A-A of Fig. 1, and

15 Fig. 3 is a section along the line A-A of Fig. 1 but with the bag in the closed form and including a packed article.

The sterilising bag of the invention illustrated in Figs. 1 and 2 in the open form comprises two rectangular, substantially flat and flexible sheets 10 and 11 of essentially the same size. Sheet 10 is made of paper which is gas- and steam-permeable and capable of serving as a bacteria filter and sheet 11 is made of gas- and steam impermeable thermoplastics material, for example polypropylene or a laminate of polypropylene with nylon or a polyester. Between sheets, 10 and 11 is a third sheet 12 in register with sheets 10 and 11 apart from at one short side 13 of the rectangle where the third sheet 12 does not extend to the edge of sheets 10 and 11. The third sheet 12 is made of a thermoplastics material-paper laminate, for example, a polypropylene-paper laminate, and is located so that the paper layer of the laminate is against the thermoplastics material sheet 11 and the thermoplastics material layer is against the paper sheet 10. The three sheets are united together by a heat formed seal 14 between the paper and thermoplastics material along the long sides 15, 16 of the rectangle and along that end 13 of the rectangle not reached by the third sheet 12. The resulting structure can thus be opened at one end to give a bag which is V-shaped in longitudinal section as illustrated in Fig. 2.

The sterilising bag of the invention may be converted into its closed form including a packed article by being loaded with a packed article 17 through its open end and then being heat sealed along the area between the dotted lines 18, 19 shown in Fig. 1. The resulting package is illustrated in Fig. 3 where the packed article 17 is located in a pocket formed between the thermoplastics material sheet 11 and the paper layer of the laminated sheet 12, and is enclosed by heat formed seals 14, 20 describing a rectangle round the packed article 17. Finger holds 21, 22 are formed beyond the seal 20.

In use, the closed bag and its packed article 17 are subjected to steam sterilisation during which the steam enters the package through the paper sheet 10, principally

through that area 23 between the end of the third sheet 12 and the seal 14. The packed article becomes sterilised, and after completion of the operation remains sterile by virtue of the sheet 10 acting as a bacteria filter.

When it is desired to release the packed article 17, the package is placed with the paper sheet 10 uppermost. The finger holds 21 and 22 are grasped so that the sheets 11 and 12 are held in one hand and the sheet 10 in the other hand. The sheet 10 is then peeled from the other two sheets by breaking the seal 20 and subsequently the seals along the sides 15, 16 of the package. Once the paper sheet 10 has been peeled off beyond the end of sheet 12 adjacent the end 13 of the package, the packed article 17 can be slid from its pocket onto the inside, and still sterile, surface of the peeled off portion of the paper sheet 10. During the operation of opening the package the packed article 17 is protected by the laminated sheet 12 from stray fibres dislodged from the paper sheet 10.

While the above specific embodiment of the invention is in the form of a rectangular bag, there is no reason why the bag should not be any convenient polygonal shape provided that the laminated sheet terminates inside the sealing line for part of the circumference of the polygon. Additional seals and perforations can also be provided for easier opening of the package, if desired.

The sterilising bag of the invention may be manufactured from three continuous strips corresponding to sheets 10, 11 and 12 having widths corresponding to the lengths of the longitudinal edges 15, 16 of the finished bag for sheets 10 and 11 and having a smaller width for sheet 12. The sheets are superposed, and sealed together, along the continuous edges 13 and transversely along lines corresponding to edges 15, 16 to produce a series of bags joined together. The individual bags are then separated by cutting along the edges 15 and 16.

#### WHAT WE CLAIM IS:—

1. A sterilising bag comprising, in its open form, two substantially flat and flexible sheets of approximately the same size, of which one is made of paper being gas- and steam-permeable and capable of serving as a bacteria filter and the other is made of practically gas- and steam-impermeable thermoplastics material, and a third sheet, having a smaller extension in one direction than the other two sheets and made of a laminate composed of a layer of thermoplastics material and a layer of paper united together: the first two sheets being united together in register with the third sheet between them by a heat formed seal along lines describing a polygon with one side

missing such that the thermoplastics material layer of the laminate is united to the paper sheet and the paper layer of the laminate is united to the thermoplastics material sheet, 5 and wherein the third sheet terminates inside the sealing line polygon for a part of its circumference remote from the unsealed side of the polygon, and is not sealed to the other two sheets along this part of its circumference. 10

2. A bag as claimed in claim 1 wherein the practically gas- and steam-impermeable thermoplastics material is polypropylene or a laminate of polypropylene with nylon 15 or a polyester.

3. A bag as claimed in claim 1 or 2 wherein the laminate composed of a layer of thermoplastics material and a layer of paper is a polypropylene-paper laminate. 20

4. A bag as claimed in claim 1, 2 or 3 wherein the polygon is a rectangle.

5. A method of using a sterilising bag as claimed in any of claims 1 to 4 to form a sterilisable bag package which comprises loading the sterilising bag with an article 25 through its unsealed side and forming a heat seal along that side to complete the polygon around the article.

6. A sterilisable bag package comprising a sterilising bag as claimed in any of claims 1 to 4 including a packed article within the bag and a heat formed seal along the unsealed side of the polygon to complete the seal around the packed article. 30

7. A sterilising bag substantially as hereinbefore described with reference to and as illustrated in Figures 1 and 2. 35

8. A sterilisable bag package substantially as hereinbefore described with reference to and as illustrated in Figure 3. 40

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FIG. 1.

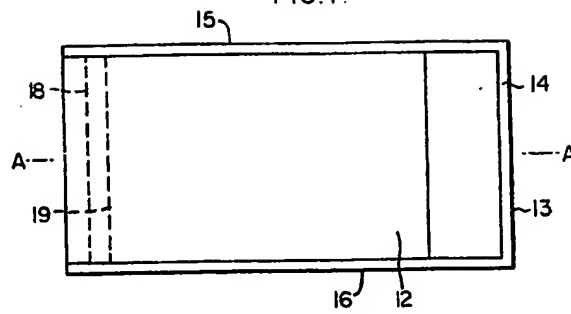


FIG. 2.

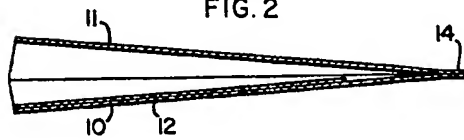


FIG. 3.

